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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/573,014

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08/10/2010

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EXAMINER

KASSA, TIGABU

ART UNIT

PAPER NUMBER

1619

MAIL DATE

DELIVERY MODE

08/10/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/573,014	Applicant(s) COHEN STUART ET AL.	
	Examiner TIGABU KASSA	Art Unit 1619	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 February 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 60-78 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 60-78 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 March 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Formal Matters

Applicants' amendment filed on 02/26/2010 is acknowledged and entered.

Claims 60-78 are under consideration in the instant office action. Claims 1-59 are cancelled. Applicants newly added claims 60-78. Applicants' amendment has necessitated a new ground of rejections. Accordingly, this Action is FINAL.

Since applicants have received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. See 37 CFR 1.142(b) and MPEP § 821.03.

Priority

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed in parent Application No. EPO 03078031.6, filed on 09/25/03. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Rejections Withdrawn

Rejections over cancelled claims are withdrawn as moot in light of Applicant's cancellation of the claims.

New Claim Rejections – Necessitated by Amendment

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 60-61, 63-64, 66-67, 68, 70-71, and 73-76 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harada et al. (Science, 283, 65-67, 1999) in view of Decher (Science, 277, 1232-1237, 1997).

Applicant Claims

Applicants claim a process for the modification or the treatment of a surface of a device to render at least one surface of said device protein-resistant, comprising the step of: coating said surface with a composition comprising at least one polymeric micelle comprising a hydrophilic, neutral corona and a complex coacervate core formed by charge complexation, wherein the polymeric micelle comprises oppositely-charged first and second polymers, wherein said first polymer comprises a block polymer comprising an ionic block and a hydrophilic neutral block, and further wherein said ionic block comprises at least 6 chargeable groups. The dependent claims thereof recite the intended uses of the surface treatment, types of polymer, and processes of treating the surface.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

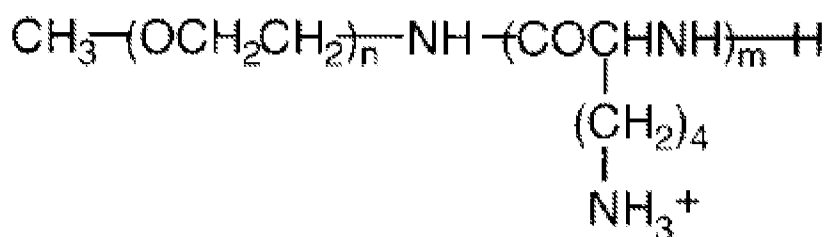
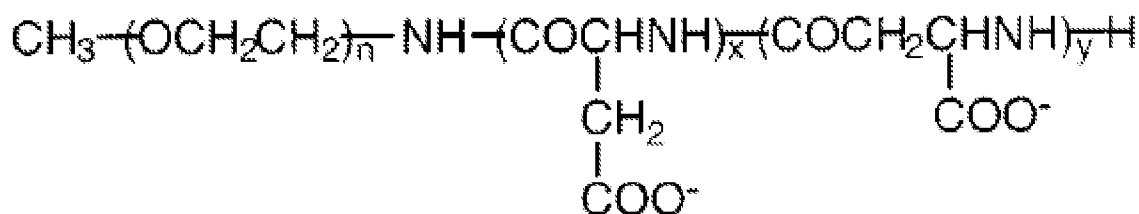
Harada et al. teach that molecular recognition based on length was found to occur between oppositely charged pairs of flexible and randomly coiled block copolymers in an aqueous milieu (see abstract). Matched pairs with the same block lengths of polyanions and polycations exclusively formed even in mixtures with different block lengths (see abstract). These assemblies of the charged segments with matched chain lengths then formed larger core-shell-type supramolecular assemblies with an extremely narrow size distribution due to the strict phase separation between core-

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and shell-forming segments (see abstract). **Harada et al. teach** a molecular

recognition system that uses assembly of coiled block copolymers (page 65).

Exclusive pair wise recognition of oppositely charged polymer strands occurs selectively on the basis of length, creating multimolecular micellization of pairs of oppositely charged block copolymers in aqueous solution (page 65). The block copolymers used here were composed of oppositely charged pairs of poly(ethylene glycol)-b-poly(α,β - aspartic acid) and poly(ethylene glycol)-b-poly(L-lysine) (page 65).



Harada et al. teach that block copolymers were synthesized by the ring-opening polymerization of *N*-carboxyanhydride of the amino acids β -benzyl-L-aspartate or ϵ -benzyloxycarbonyl-L-lysine, initiating from the ω -NH₂ group of α -methoxy- ω -aminopoly(ethylene glycol) (page 65). The molecular weight (M_w) of the PEG segment was fixed at 5000 g/mol for all block copolymers examined in this study (page 65). After

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polymerization, protecting groups on the poly(amino acid) segments were removed either by alkali treatment (β -benzyl-L-aspartate) or by acid treatment (ϵ -benzyloxycarbonyl-L-lysine). Block copolymers thus obtained were confirmed to have a fairly narrow M_w distribution [ratio of the weight-averaged to number-averaged molecular weight (M_w/M_n) < 1.10] by gel filtration chromatography (GFC) (page 65). For both anionic and cationic partners, two sets of copolymers with different degree of polymerization of poly(amino acid) segments (18 and 78) were prepared and were abbreviated as A-18 and A-78 and as C-18 and C-78, respectively (page 65). Addition of either C-18 or C-78 to the mixture of A-18 and A-78 resulted in the formation of narrowly distributed PIC micelles with diameters corresponding to those of micelles prepared from the matched pair, as did the analogous experiment for polyanion addition (page 66). Because polvion complex (PIC) micelles from A-18/C-18 had a M_w of about 5×10^5 g/mol, which corresponds to an association number of approximately 40 chains of both A-18 and C-18 (PAGE 66). The M_w increased to 3×10^6 g/mol for the A-78/C-78 pair, corresponding to a total of 180 chains (90 chains each for A-78 and C-78) (Page 66). The examiner calculates the ratio of total number of cationic polymeric groups to total number of charged groups in the resulting mixture is to be 40/80 or 90/180 which is 0.5. With regard the intended use limitations recited in claims 61 and 66-67, since the prior art structure is substantially similar to the instantly claimed structure it would necessarily be capable of doing the intended uses. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is similar and is capable of performing the recited intended uses the prior art reference

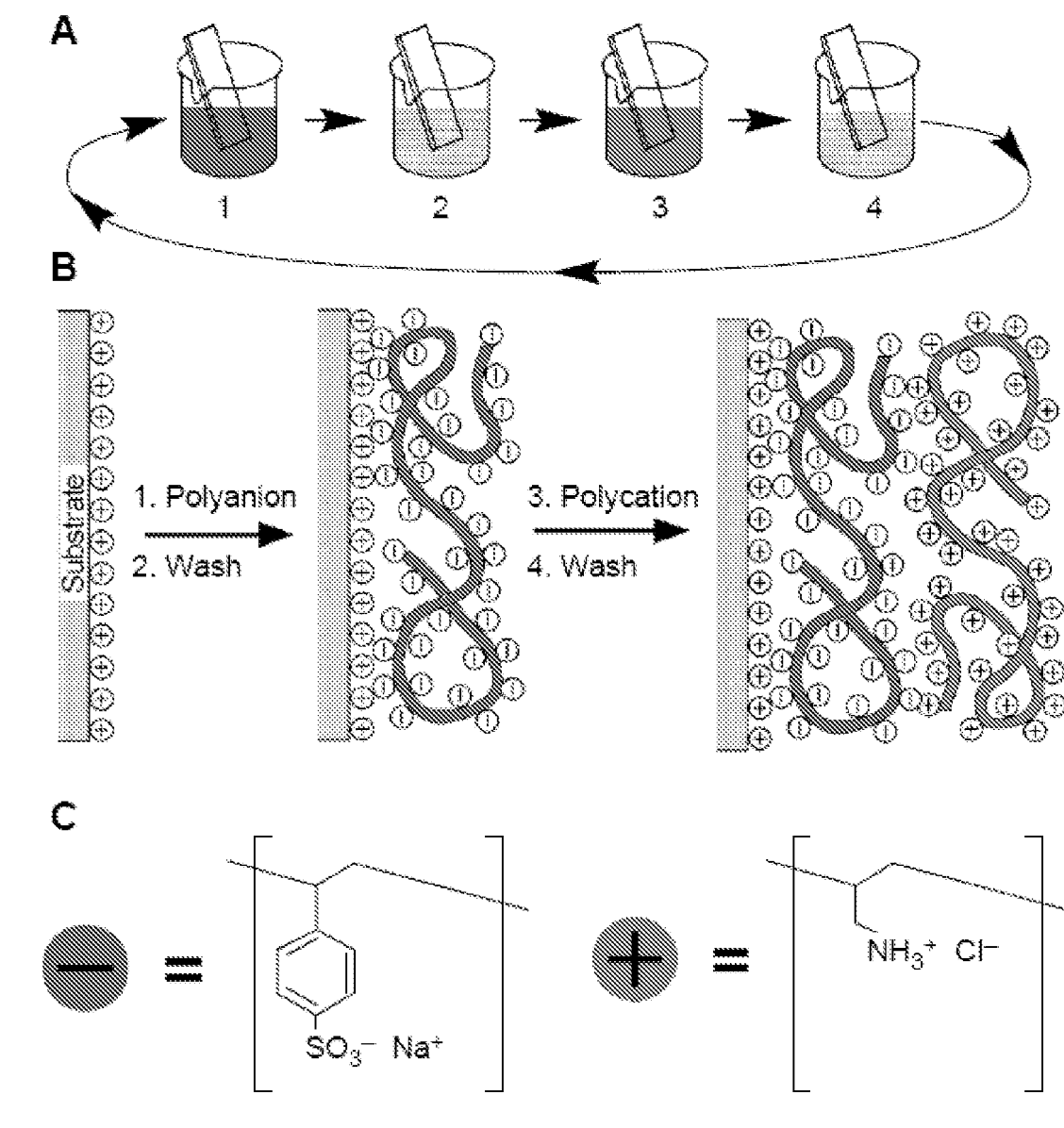
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clearly meets the limitations. The 90 chain block copolymer units taught by Harada et al absent of unexpected results would behave very similarly to the instantly claimed limitation reciting that the second polymer comprises at least 100 charged monomeric units.

***Ascertainment of the Difference between Scope the Prior Art and the Claims
(MPEP §2141.012)***

Harada et al. do not explicitly teach coating a surface with the oppositely charged polymeric micelle structures. This deficiency is cured by the teachings of Decher.

Harada et al. teach in their conclusive remarks section assembly of charged block copolymers in aqueous medium may lead to the formation of similar higher ordered structures through precise recognition based on the chain lengths of charged segments, which may be useful for constructing self-assembled layers based on electrostatic interaction by citing the reference Decher (Science, 277, 1232-1237, 1997) (page 67). One of ordinary skill in the art would have inferred from the teachings of Harada et al. above that the application delineated by Decher is equally applicable to the application of the PIC micelles of Harada et al. Decher teaches multilayer structures composed of polyions or other charged molecular or colloidal objects (or both) are fabricated as schematically outlined below (page 1233)



A) Schematic of the film deposition process using slides and beakers. Steps 1 and 3 represent the adsorption of a polyanion and polycation, respectively, and steps 2 and 4 are washing steps. The four steps are the basic buildup sequence for the simplest film architecture, $(A/B)_n$. The construction of more complex film architectures requires only additional beakers and a different deposition sequence. **(B)** Simplified molecular picture

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of the first two adsorption steps, depicting film deposition starting with a positively charged substrate. The polyion conformation and layer interpenetration are an idealization of the surface charge reversal with each adsorption step. (C) Chemical structures of two typical polyions, the sodium salt of poly(styrene sulfonate) and poly(allylamine hydrochloride).

Decher teaches in its conclusion remarks that layer-by-layer assembly by adsorption from solution is a general approach for the fabrication of multicomponent films on solid supports (page 1236). Materials can be selected from a pool of small organic molecules, polymers, natural proteins, inorganic clusters, clay particles, and colloids (page 1236).

***Finding of Prima Facie Obviousness Rationale and Motivation
(MPEP §2142-2143)***

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the polymeric micelles of Harada et al. on a device surfaces because Harada et al. themselves teach in their conclusive remarks section assembly of charged block copolymers in aqueous medium may lead to the formation of similar higher ordered structures through precise recognition based on the chain lengths of charged segments, which may be useful for constructing self-assembled layers based on electrostatic interaction by citing the reference Decher (Science, 277, 1232-1237, 1997). The skilled artisan would have been motivated to coat device surfaces with polymeric micelles having oppositely charged assembly because Decher teaches in its conclusion remarks that layer-by-layer assembly by adsorption from solution is a

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general approach for the fabrication of multicomponent films on solid supports

(page 1236). Materials can be selected from a pool of small organic molecules, polymers, natural proteins, inorganic clusters, clay particles, and colloids (page 1236). Additionally, in the case where the claimed ranges “overlap or lie inside ranges disclosed by the prior art” a *prima facie* case of obviousness exists. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990). Generally, differences in concentration, number of chargeable polymeric units, or ratios will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). A skilled artisan would have had a reasonable expectation of success in combining Harada et al. and Decher, because both references teach similar polyion based structures that assemble themselves based on opposite charge interactions.

In light of the forgoing discussion, one of ordinary skill in the art would have concluded that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the reference, especially in the absence of evidence to the contrary.

Claims 62, 65, 69, 71-72, 77-78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harada et al. (Science, 283, 65-67, 1999) in view of Decher (Science, 277, 1232-1237, 1997), as applied to claims 60-61, 63-64, 66-67, 68, 70-71, and 73-76 above, and further in view of Karymov et al. (Langmuir, 12, 4748-4753, 1996).

Applicant Claims

The claimed subject matters of instant claims 60 and 68 are set forth above. The dependent claims thereof recite what the ionic block polymer and the second polymer comprise. Instant claims 77-78 recite similar subject matters as in the above recited claims the lists of ionic block polymers and the second polymer are incorporated.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Harada et al. and Decher are set forth above.

Ascertainment of the Difference between Scope the Prior Art and the Claims (MPEP §2141.012)

Harada et al. do not explicitly teach the list of polymers that the ionic block and the second polymer comprises. This deficiency is cured by the teachings of Karymov et al.

Karymov et al. teach chemical attachment of polystyrene-block-poly(methacrylic acid) micelles on a silicon nitride surface (title). Karymov et al. teach that polystyrene-block-poly(methacrylic acid) micelles were chemically attached to an activated silicone nitride surface using a 1-(3-(dimethylamino)propyl-3-ethylcarbodiimide methiodide coupling reaction (see abstract). It is clearly noticed that from the teachings of Karymov

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et al. the potential of block copolymers containing polymethacrylic acid for forming polymeric micelles for coating surfaces.

Finding of Prima Facie Obviousness Rationale and Motivation
(MPEP §2142-2143)

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was to modify the polymeric micelles of Harada et al. by incorporating polymeric blocks comprising such as polymethacrylic acid for forming micelles because Karymov et al. teach chemical attachment of polystyrene-block-poly(methacrylic acid) micelles on a silicon nitride surface (title). The skilled artisan would have been motivated to substitute for example the block copolymer poly(ethylene glycol)-b-poly(α,β - aspartic acid) with the block copolymer of Karymov et al. because they are functionally equivalent because of the availability of a chargeable negative charge both on polyaspartic acid in the case of Harada et al. and polymethacrylic acid in the case of Karymov et al. A skilled artisan would have had a reasonable expectation of success in combining Harada et al. and Karymov et al. because both references teach the use of polymeric micelles for coating surfaces.

In light of the forgoing discussion, one of ordinary skill in the art would have concluded that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the reference, especially in the absence of evidence to the contrary.

Conclusion

Claims 60-78 are rejected. Claims 1-59 are cancelled. Applicants added new claims 60-78.

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIGABU KASSA whose telephone number is (571)270-5867. The examiner can normally be reached on 9 am-5 pm Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne P. Eyler can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Tigabu Kassa

7/26/10

/Cherie M. Woodward/
Primary Examiner, Art Unit 1647